



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,099	04/15/2004	Hui-Yin Li	PH 7115 DIV2	9263

23914 7590 08/18/2005

STEPHEN B. DAVIS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,099

Applicant(s)

LI ET AL.

Examiner

Rebecca L. Anderson

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22, 28 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) 17-22 and 32-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date June 28, 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1626

DETAILED ACTION

Claims 17-22, 28 and 32-37 are currently pending in the instant application.

Claims 17-22 and 32-37 are withdrawn from consideration as being for non-elected subject matter. Claim 28 is rejected.

Election/Restrictions

Applicant's election of Group II, claim 28 in the reply filed on 7 June 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The examiner confirms that upon a time that the product claim of 28 is found allowable, process claims depending from or otherwise including all of the limitations of the product claim will be subject to rejoinder. However, at this time, the product claim 28 is rejected and claims 17-22 and 32-37 are considered withdrawn from consideration as being for non-elected subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

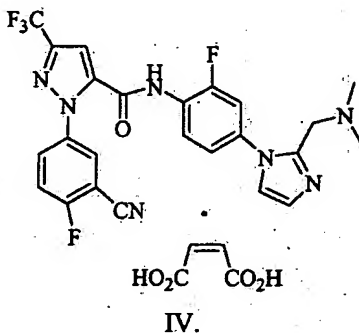
Art Unit: 1626

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/32454.

Applicants' instant claim 28 claims a compound of formula IV:



Determining the scope and contents of the prior art

WO 99/32454 discloses compounds, which are inhibitors of factor Xa useful for the treatment of thromboembolic disorders (page 1), of the formula I (page 4) wherein

Art Unit: 1626

ring M can contain an additional nitrogen atoms, J can be N, D can be CN, E can be phenyl, R can be F, G can be absent, Z can be $(CH_2)_rC(O)NR_3(CH_2)_r$, R1a and R1b can be $-(CH_2)-R_1'$, R1' can be $(CF_2)_r(CF_3)$, (pages 5-6), A can be phenyl and B can be a 5-10 membered heterocyclic system substituted with R4a, wherein R4a can be $(CH_2)_rNR_2R_{2a}$ wherein R2 and R2a can be alkyl (page 8). A more preferred embodiment of compounds are found on page 13, for example, formula IIa. Page 18 discloses another even more preferred embodiment, for example, the compound of the formula Iia wherein D is $-CN$, E is phenyl substituted with R which can be F, Z is $C(O)NH$, R1a can be $-(CH_2)_r-R_1'$, R1' can be $(CF_2)_rCF_3$, A is phenyl substituted with R4 which can be F, B is Y which can be imidazolyl substituted with 0-2 R4a which can be $(CH_2)_rNR_2R_{2a}$ (page 19). Another further preferred embodiment has the compound of the formula IIa wherein E is phenyl, R can be F, Z is $C(O)NH$, R1a can be CF_3 , R1b is H, A is phenyl, B is imidazolyl, R2 and R2a can each be CH_3 and R4a can be $CH_2NR_2R_{2a}$ (page 20-21). Page 38 discloses the pharmaceutically acceptable salts, such as, for example, organic acid salts such as maleic acid.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art reference and claim 28 at issue is that the prior art reference generically encompass applicants instantly claimed maleic acid salt of the product of claim 28 and provide preferences towards applicants instant product of claim 28, but do not specifically disclose a maleic acid salt of the product as instantly claimed.

Resolving the level of ordinary skill in the pertinent art

However, it would have been obvious to someone of ordinary skill in the art at the time of the invention, when faced with WO 99/32454 to prepare the maleic acid salt of the product as instantly claimed in claim 28 as the prior art reference provides compounds which are useful as factor Xa inhibitors and generically encompasses applicants instantly claimed product, provides preferences towards applicants instantly claimed product and provides maleic acid as a pharmaceutically acceptable salt. The motivation to prepare applicants' instantly claimed compound comes from the preferred embodiments of the prior art reference and the expectation of preparing additional compounds useful for the treatment of thromboembolic disorders.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

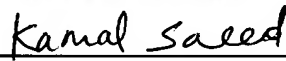
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600
8/11105

KAMAL A. SAEED, PH.D.

PRIMARY EXAMINER

for 

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600